and includes the amino acid sequence of SEQ ID NO: 2 and 4 that were disclosed in Figures 1A and 2A, respectively. The content of the substitute sequence listing information recorded in computer readable form (submitted herewith) is identical to the paper copy of the sequence listing attached hereto. The amendments to the specification at page 16, lines 1, 7, and 16 have been made to correct obvious typographical errors, support for which is found in Figures 1A-1B and 2A-2B. No new matter is added by virtue of the amendments to the specification. Accordingly, entry of the forgoing amendment into the instant application is kindly solicited.

The Examiner identified errors in page 5 of the specification; these errors have been rectified by the amendments to the sequence listing mentioned above.

Formal Matters

Applicant notes the 1449 form returned with the Office Action included four references that were crossed out because no dates were provided. Applicant is submitting a modified Form PTO - 1449 herewith, including the requested dates. Consideration of these references is therefore requested.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1, 3, 4 and 6-8 were rejected under 35 U.S.C. §112, first paragraph, based on a lack of written description in the specification. The Examiner asserts that "the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 3 alone is insufficient to describe the genus." See Office Action, page 4. The Examiner concludes that "Applicant's have not described a function which is shared by SEQ ID NO: 3 which would adequately describe the genus." See Office Action, page 4. However, Applicant respectfully submits that the invention is indeed adequately described in the specification.

In order to comply with the written description requirement, an Applicant's specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, i.e., whatever is now claimed. *Vas Cath Inc. v. Mahurkar,* 19 USPQ 1111, 1117 (Fed. Cir. 1991) (cited in MPEP § 2163 and in the Examiner Guidelines on Written Description Requirement). The Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an Applicant's disclosure a description of the invention defined by the claims. *In re Wertheim,* 191

USPQ 90 (CCPA 1976) (cited in MPEP § 2163.04 in the Examiner Guidelines on Written Description Requirement). Determining whether the written description is satisfied requires reading the disclosure in light of the knowledge possessed by those skilled in the art. *In re Alton,* 37 USPQ2d 1578 (Fed. Cir. 1996). Applying these tenets, Applicant submits that the Office has failed to carry its burden as the Office has failed to supply any "evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." *In re Wertheim,* 191 USPQ 90 (CCPA 1976). In fact, a review of the application as a whole evidences that the application is more than sufficient to convey with reasonable clarity to those skilled in the art that, as of the filing date sought, they were in possession of the previously claimed invention.

The nucleic acid molecules of claim 1 code for an "immunogenic" polypeptide. The nucleic acid molecules of claim 3 also code for an "immunogenic" polypeptide that has "80% identity" to nucleotide positions 9 to 587 of SEQ ID NO: 3. Thus, the Applicant has indeed provided a common attribute and characteristic for nucleic acid molecules that fall within the recitation of the claims, namely, that the molecules encode proteins that are immunogenic.

The specification on page 9 defines the term "immunogenic." In particular, an immunogenic polypeptide refers to a polypeptide which elicits an immunological response. An "immunological response" is the development in a host of a cellular and/ or antibody-mediated immune response. Several techniques are well known in the art to detect immunological responses of polypeptides. Hence, a person of skill in the art can identify nucleic acid molecules that encode "immunogenic" polypeptides. Further, examples of techniques to detect an immunological response are provided in the specification, specifically in Examples 3, 4, and 5.

Thus, it is readily apparent that one of skill in the art would recognize that the Applicant was in possession of the claimed invention at the time the application was filed. Withdrawal of this rejection is therefore respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected 35 U.S.C. § 112, second paragraph as being indefinite. Applicant has deleted the term "about" from claim 3. Hence, Applicant believes the rejection is moot and respectfully requests its withdrawal.

Rejection under 35 U.S.C. § 102

The Examiner has rejected claims 1, 4, and 7-8 under 35 U.S.C. § 102(e) as being anticipated by Perryman *et al.* (U.S. Patent Number: 6,323,020). The Examiner has pointed out Perryman *et al.* discloses an isolated nucleic acid comprising a DNA coding sequence for an immunogenic *C. parvum* polypeptide with a molecular weight of 23 kDa. The Examiner asserts that as the "Applicant's specification sets forth the *C. parvum* antigenic polypeptide 2 is determined to be 21.8 kDa, and that the nucleic acid disclosed by Perryman *et al* encodes a *C. parvum* polypeptide with a molecular weight of 23 kDa, the disclosure of Perryman *et al*" anticipates the claimed invention.

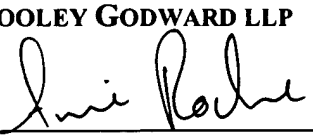
Applicant respectfully traverses this rejection. Applicant has performed BLAST® analyses of the nucleotide sequences of SEQ ID NO: 3. First, the only sequence with significant alignment was sequence 3 from PCT publication WO0196370, which is the corresponding PCT application of the pending application. Second, the nucleotide sequences of SEQ ID NO: 3 (1323 nucleotides) of the pending application were compared to SEQ ID NO: 1 (602 nucleotides) of Perryman *et al.* and no significant homology was observed. Lastly, the amino acid sequences of SEQ ID NO: 4 (193 amino acids) of the pending application were compared to SEQ ID NO: 2 (111 amino acids) of Perryman *et al.* and no significant homology was observed. Hence, Applicant respectfully asserts that Perryman *et al.* does not anticipate the claimed invention and respectfully requests the withdrawal of the rejection.

CONCLUSION

Applicant respectfully submits that the claims are novel and nonobvious over the art and comply with the requirements of 35 U.S.C. §112. Accordingly, allowance is believed to be in order and an early notification to that effect would be appreciated.

Dated: March 31, 2003

Respectfully submitted,
COOLEY GODWARD LLP

By: 

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CURRENTLY PENDING CLAIMS

1. **(AMENDED)** An isolated nucleic acid molecule comprising a coding sequence for an immunogenic *C. parvum* polypeptide selected from the group consisting of a *C. parvum* antigenic polypeptide 2 (AG2), or a fragment of said nucleic acid molecule comprising at least 15 nucleotides.

3. **(AMENDED)** The nucleic acid molecule of claim 1 wherein said molecule comprises a nucleotide sequence having at least 80% identity to the nucleotide sequence shown at nucleotide positions 9-587, inclusive, of Figure 2A (SEQ ID NO: 3), or a fragment thereof comprising at least about 15 nucleotides.

4. A recombinant vector comprising:

(a) a nucleic acid molecule according to claim 1; and

(b) control elements that are operably linked to said nucleic acid molecule whereby said coding sequence can be transcribed and translated in a host cell, and at least one of said control elements is heterologous to said coding sequence.

6. A recombinant vector comprising:

(a) a nucleic acid molecule according to claim 3; and

(b) control elements that are operably linked to said nucleic acid molecule whereby said coding sequence can be transcribed and translated in a host cell, and at least one of said control elements is heterologous to said coding sequence.

7. A host cell transformed with the recombinant vector of claim 4.

8. A method of producing a recombinant *C. parvum* antigenic polypeptide comprising:

(a) providing a population of host cells according to claim 7; and

(b) culturing said population of cells under conditions whereby the antigenic polypeptide encoded by the coding sequence present in said recombinant vector is expressed.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Paragraph beginning at page 16, line 1, has been amended as follows:

The cDNA and predicted amino acid sequences of AG1 and AG2 are shown in Figures 1A-1B and 2A-2B, respectively. Perfect and imperfect consensus polyadenylation signals are underlined and N-glycosylation sites are in bold face type. The DNA sequence of AG1 is also shown in SEQ ID NO: 1, while SEQ ID NO: 3 shows the complete DNA sequence of AG2. The predicted amino acid sequences for AG1 and AG2 are shown in [SEQ ID NOs: 1 and 2] SEQ ID NO: 2 and [SEQ ID NOs: 3 and 4] SEQ ID NO: 4, respectively.

Paragraph beginning at page 16, line 7, has been amended as follows

As described in the examples, full-length *ag1*, depicted at nucleotide positions 8-394, inclusive, of Figure 1A, encodes a full-length AG1 protein of approximately 129 amino acids, shown as amino acids 1-129, inclusive, of Figure 1A (SEQ ID NO: 2). The 3' untranslated region is 945 nucleotides long, from positions 395-1338 of [Figure 1A] Figures 1A-1B (SEQ ID NO: 1). Imperfect polyadenylation signals occur at positions 1241-1245 and 1307-1311. The sequence (SEQ ID NO: 1) has been assigned GenBank Accession Number AF178459. The protein encoded by the predicted open reading frame (ORF) has a predicted molecular weight of about 15 kDa. The predicted isoelectric point is pH 9.6 and 44% of the predicted amino acid residues are hydrophobic. Two N-linked glycosylation sites have been identified at amino acid residues 36-38 and 71-73.

Paragraph beginning at page 16, line 16, has been amended as follows

Full-length *ag2*, depicted at nucleotide positions 9-587, inclusive, of Figure [1B] 2A, encodes a full-length AG2 protein of approximately 193 amino acids, shown as amino acids 1-193, inclusive, of Figure [1B] 2A (SEQ ID NO: 4). The 3' untranslated region is 712 nucleotides long, from positions 588-1298 of [Figure 1B] Figures 2A-2B (SEQ ID NO: [2] 4). Imperfect polyadenylation signals occur at positions 945-949 and 1141-1145. The sequence (SEQ ID NO:

3) has been assigned GenBank Accession Number AF178460. The protein encoded by the predicted open reading frame (ORF) has a predicted molecular weight of about 21.8 kDa. The predicted isoelectric point is pH 6.23 and 36% of the predicted amino acid residues are hydrophobic. Two N-linked glycosylation sites were identified at amino acid residues 36-38 and 51-53.

IN THE CLAIMS

Please amend claims 1 and 3 as follows:

1. **(AMENDED)** An isolated nucleic acid molecule comprising a coding sequence for an immunogenic *C. parvum* polypeptide selected from the group consisting of [(a) a C. parvum antigenic polypeptide 1 (AG1) and (b)] a *C. parvum* antigenic polypeptide 2 (AG2), or a fragment of said nucleic acid molecule comprising at least 15 nucleotides.

3. **(AMENDED)** The nucleic acid molecule of claim 1 wherein said molecule comprises a nucleotide sequence having at least [about] 80% identity to the nucleotide sequence shown at nucleotide positions 9-587, inclusive, of Figure [1B] 2A (SEQ ID NO: 3), or a fragment thereof comprising at least about 15 nucleotides.